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08/803,702

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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY DOCKET NO
08/803,702	02/21/97	MAINO	V P-3639P1

EXAMINER

HM12/1213

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ART UNIT	PAPER NUMBER
1644	19

DATE MAILED: 12/13/99

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☑ Responsive to communication(s) filed on 3/12/99

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☑ Claim(s) 19-60 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☐ Claim(s) _____ is/are rejected.
☐ Claim(s) _____ is/are objected to.
☑ Claim(s) 19-60 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
☐ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

DETAILED ACTION

1. The location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1644, Technology Center 1600.

2. Applicant's amendment, filed 3/12/99 (Paper No. 10), is acknowledged.
Claims 1-18 have been canceled.
Claims 19-60 have been added.

3. **Please Note**: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-305-3704. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

4. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 19-55, drawn to methods detecting antigen-specific cytokine production, classified in Class 435, subclass 7.1

II. Claim 56, drawn to methods of detecting memory/effector T cells that respond to a vaccine antigen, classified in Class 435, subclass 7.1.

III. Claim 57, drawn to methods of assessing $CD4^+$ T cells frequencies in HIV subjects, classified in Class 435, subclass 7.1

IV. Claim 58-60, drawn to methods of assessing immunomodulatory effects of a chemical compound, classified in Class 7.1.

5. Inventions I/II/III/IV are different methods, which require different ingredients, process steps and endpoints. Therefore, they are patentably distinct.

6. Because these inventions are distinct for the reasons given above and the search required for any group from Groups I-IV is not required for any other group from Groups I-IV and Groups I-IV have acquired a separate status in the art because the searches are not co-extensive and encompass divergent subject matter, restriction for examination purposes as indicated is proper.

7. If applicant elects Group I; then applicant must elect one from each of the following

A) This application contains claims directed to the following patentably distinct species of the claimed Group I wherein the cytokine-specific antibody is:

I) anti-IL-2,
ii) anti-IL4,
iii) anti-γIFN, or
iv) anti-TNF-α.

These species are distinct because their structures and modes of action are different. Also, it is noted that the targeted specificities differ with respect to their structure; a person of ordinary skill in the art would not envision one in view of the other. They are therefore separate and patentably distinct species in view of each other.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

B) This application contains claims directed to the following patentably distinct species of the claimed Group I: wherein the subset-defining antibody is:

I) anti-CD3,
ii) anti-CD4,
iii) anti-CD8,
iv) anti-TCR,
v) anti-homing receptors (raises 112, first and second paragraph, issues),
vi) anti-CD40RO,
vii) anti-CD45RA, or
viii) anti-CD27.

These species are distinct because their structures and modes of action are different. Also, it is noted that the targeted specificities differ with respect to their structure, a person of ordinary skill in the art would not envision one in view of the other. They are therefore separate and patentably distinct species in view of each other.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

C) This application contains claims directed to the following patentably distinct species of the claimed Group I wherein the costimulus is:

I) anti-CD28 antibody or
ii) anti-VLA-4 antibody

These species are distinct because their structures and modes of action are different. Also, it is noted that the targeted specificities differ with respect to their structure, a person of ordinary skill in the art would not envision one in view of the other. They are therefore separate and patentably distinct species in view of each other.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

D) This application contains claims directed to the following patentably distinct species of the claimed Group I wherein the nominal antigen is

I) alloantigen,
ii) viral antigen (recited twice in claim 31),
iii) autoantigen, or
iv) bacterial antigen.

These species are distinct because their structures and modes of action are different. The sequences differ with respect to their structure, a person of ordinary skill in the art would not envision one in view of the other. They are therefore separate and patentably distinct species in view of each other.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

E) If applicant elects viral antigen; then applicant must elect one of the following.
This application contains claims directed to the following patentably distinct species of the claimed Group I wherein the viral antigen is

I) CMV antigen,
Ii) HIV antigen,
iii) mumps antigen, or
iv) measles antigen.

These species are distinct because their structures and modes of action are different. The sequences differ with respect to their structure, a person of ordinary skill in the art would not envision one in view of the other. They are therefore separate and patentably distinct species in view of each other.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

8. If applicant elects Group II; and given the disclosure of the following species then applicant must elect one from each of the following.

A) This application contains claims directed to the following patentably distinct species of the claimed Group II wherein the cytokine-specific antibody is:

I) anti-IL-2,
ii) anti-IL4,
iii) anti-γIFN, or
iv) anti-TNF-α.

These species are distinct because their structures and modes of action are different. Also, it is noted that the targeted specificities differ with respect to their structure; a person of ordinary skill in the art would not envision one in view of the other. They are therefore separate and patentably distinct species in view of each other.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 56 is generic.

B)) This application contains claims directed to the following patentably distinct species of the claimed Group I wherein the nominal antigen is

I) alloantigen,
ii) viral antigen (recited twice in claim 31),
iii) autoantigen, or
iv) bacterial antigen.

These species are distinct because their structures and modes of action are different. The sequences differ with respect to their structure, a person of ordinary skill in the art would not envision one in view of the other. They are therefore separate and patentably distinct species in view of each other.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 56 is generic.

C) If applicant elects viral antigen; then applicant must elect one of the following.
This application contains claims directed to the following patentably distinct species of the claimed Group I wherein the viral antigen is

I) CMV antigen,
Ii) HIV antigen,
iii) mumps antigen, or
iv) measles antigen.

These species are distinct because their structures and modes of action are different. The sequences differ with respect to their structure, a person of ordinary skill in the art would not envision one in view of the other. They are therefore separate and patentably distinct species in view of each other.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 56 is generic.

9. If applicant elects Group III; and given the disclosure of the following species then applicant must elect one from each of the following.

A) This application contains claims directed to the following patentably distinct species of the claimed Group III wherein the cytokine-specific antibody is:

I) anti-IL-2,
ii) anti-IL4,
iii) anti-γIFN, or
iv) anti-TNF-α.

These species are distinct because their structures and modes of action are different. Also, it is noted that the targeted specificities differ with respect to their structure; a person of ordinary skill in the art would not envision one in view of the other. They are therefore separate and patentably distinct species in view of each other.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 57 is generic.

B)) This application contains claims directed to the following patentably distinct species of the claimed Group III wherein the nominal antigen is

I) alloantigen,
ii) viral antigen (recited twice in claim 31),
iii) autoantigen, or
iv) bacterial antigen.

These species are distinct because their structures and modes of action are different. The sequences differ with respect to their structure, a person of ordinary skill in the art would not envision one in view of the other. They are therefore separate and patentably distinct species in view of each other.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 57 is generic.

C) If applicant elects viral antigen; then applicant must elect one of the following.
This application contains claims directed to the following patentably distinct species of the claimed Group III wherein the viral antigen is

I) CMV antigen,
Ii) HIV antigen,
iii) mumps antigen, or
iv) measles antigen.

These species are distinct because their structures and modes of action are different. The sequences differ with respect to their structure, a person of ordinary skill in the art would not envision one in view of the other. They are therefore separate and patentably distinct species in view of each other.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 57 is generic.

10. If applicant elects Group IV; and given the disclosure of the following species, then applicant must elect one from each of the following

A) This application contains claims directed to the following patentably distinct species of the claimed Group IV wherein the cytokine-specific antibody is:

I) anti-IL-2,
ii) anti-IL4,
iii) anti-γIFN, or
iv) anti-TNF-α.

These species are distinct because their structures and modes of action are different. Also, it is noted that the targeted specificities differ with respect to their structure; a person of ordinary skill in the art would not envision one in view of the other. They are therefore separate and patentably distinct species in view of each other.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 58 is generic.

B) This application contains claims directed to the following patentably distinct species of the claimed Group IV: wherein the subset-defining antibody is:
I) anti-CD3,
ii) anti-CD4,
iii) anti-CD8,
iv) anti-TCR,
v) anti-homing receptors (raises 112, first and second paragraph, issues),
vi) anti-CD40RO,
vii) anti-CD45RA, or
viii) anti-CD27.

These species are distinct because their structures and modes of action are different. Also, it is noted that the targeted specificities differ with respect to their structure, a person of ordinary skill in the art would not envision one in view of the other. They are therefore separate and patentably distinct species in view of each other.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 58 is generic.

C) This application contains claims directed to the following patentably distinct species of the claimed Group IV wherein the costimulus is:

I) anti-CD28 antibody or
ii) anti-VLA-4 antibody

These species are distinct because their structures and modes of action are different. Also, it is noted that the targeted specificities differ with respect to their structure, a person of ordinary skill in the art would not envision one in view of the other. They are therefore separate and patentably distinct species in view of each other.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 58 is generic.

D) This application contains claims directed to the following patentably distinct species of the claimed Group IV wherein the nominal antigen is

I) alloantigen,
ii) viral antigen (recited twice in claim 31),
iii) autoantigen, or
iv) bacterial antigen.

These species are distinct because their structures and modes of action are different. The sequences differ with respect to their structure, a person of ordinary skill in the art would not envision one in view of the other. They are therefore separate and patentably distinct species in view of each other.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 58 is generic.

E) If applicant elects viral antigen; then applicant must elect one of the following.
This application contains claims directed to the following patentably distinct species of the claimed Group IV wherein the viral antigen is

I) CMV antigen,
Ii) HIV antigen,
iii) mumps antigen, or
iv) measles antigen.

These species are distinct because their structures and modes of action are different. The sequences differ with respect to their structure, a person of ordinary skill in the art would not envision one in view of the other. They are therefore separate and patentably distinct species in view of each other.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 58 is generic.

11. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

12. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

13. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Serial No. 08/803702
Art Unit 1644

Phillip Gambel, PhD.
Patent Examiner
Technology Center 1600
December 10, 1999

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